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09/736,619	12/13/2000	Igor Markidan	4389-9	8901
22442	7590	12/30/2003	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			HARLE, JENNIFER I	
			ART UNIT	PAPER NUMBER
			3627	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/736,619

Applicant(s)

MARKIDAN ET AL.

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☒ Other: 37 CFR 1.105.

## **DETAILED ACTION**

Claims 1-9 are pending.

### ***Response to Arguments***

#### ***Rejection Under 35 U.S.C. §101***

Applicant's arguments, pertaining to claims 1-3 and 5, filed September 22, 2003 have been fully considered but they are not persuasive. Applicants attempt to traverse the examiners rejection because the method recited is a "useful process and therefore statutory subject matter. However, as the examiner set forth, the claimed invention is not statutory because it must full within the technological arts and this invention fails to do so. A further analysis is set forth below.

As an initial matter, the United States Constitution under Art. I, §8, cl. 8 gave Congress the power to "[p]romote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries". In carrying out this power, Congress authorized under 35 U.S.C. §101 a grant of a patent to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition or matter, or any new and useful improvement thereof." Therefore, a fundamental premise is that a patent is a statutorily created vehicle for Congress to confer an exclusive right to the inventors for "inventions" that promote the progress of "science and the useful arts". The phrase "technological arts" has been created and used by the courts to offer another view of the term "useful arts". See *In re Musgrave*, 167 USPQ (BNA) 280 (CCPA 1970). Hence, the first test of whether an invention is eligible for a patent is to determine if the invention is within the "technological arts".

Further, despite the express language of §101, several judicially created exceptions have been established to exclude certain subject matter as being patentable subject matter covered by §101. These exceptions include "laws of nature", "natural phenomena", and "abstract ideas". See *Diamond v. Diehr*, 450, U.S. 175, 185, 209 USPQ (BNA) 1, 7 (1981). However, courts have found that even if an invention incorporates abstract ideas, such as mathematical algorithms, the invention may nevertheless be statutory subject matter if the invention as a whole produces a "useful, concrete and tangible result." See *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* 149 F.3d 1368, 1973, 47 USPQ2d (BNA) 1596 (Fed. Cir. 1998).

This "two prong" test was evident when the Court of Customs and Patent Appeals (CCPA) decided an appeal from the Board of Patent Appeals and Interferences (BPAI). See *In re Toma*, 197 USPQ (BNA) 852 (CCPA 1978). In *Toma*, the court held that the recited mathematical algorithm did not render the claim as a whole non-statutory using the Freeman-Walter-Abele test as applied to *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ (BNA) 673 (1972). Additionally, the court decided separately on the issue of the "technological arts". The court developed a "technological arts" analysis:

The "technological" or "useful" arts inquiry must focus on whether the claimed subject matter...is statutory, not on whether the product of the claimed subject matter...is statutory, not on whether the prior art which the claimed subject matter purports to replace...is statutory, and not on whether the claimed subject matter is presently perceived to be an improvement over the prior art, e.g., whether it "enhances" the operation of a machine. *In re Toma* at 857.

In *Toma*, the claimed invention was a computer program for translating a source human language (e.g., Russian) into a target human language (e.g., English). The court found that the claimed

computer implemented process was within the "technological art" because the claimed invention was an operation being performed by a computer within a computer.

The decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* never addressed this prong of the test. In *State Street Bank & Trust Co.*, the court found that the "mathematical exception" using the Freeman-Walter-Abele test has little, if any, application to determining the presence of statutory subject matter but rather, statutory subject matter should be based on whether the operation produces a "useful, concrete and tangible result". See *State Street Bank & Trust Co.* at 1374. Furthermore, the court found that there was no "business method exception" since the court decisions that purported to create such exceptions were based on novelty or lack of enablement issues and not on statutory grounds. Therefore, the court held that "[w]hether the patent's claims are too broad to be patentable is not to be judged under §101, but rather under §§102, 103 and 112." See *State Street Bank & Trust Co.* at 1377. Both of these analysis goes towards whether the claimed invention is non-statutory because of the presence of an abstract idea. Indeed, *State Street* abolished the Freeman-Walter-Abele test used in *Toma*. However, *State Street* never addressed the second part of the analysis, i.e., the "technological arts" test established in *Toma* because the invention in *State Street* (i.e., a computerized system for determining the year-end income, expense, and capital gain or loss for the portfolio) was already determined to be within the technological arts under the *Toma* test. This dichotomy has been recently acknowledged by the Board of Patent Appeals and Interferences (BPAI) in affirming a §101 rejection finding the claimed invention to be non-statutory. See *Ex parte Bowman*, 61 USPQ2d (BNA) 1669 (BdPatApp&Int 2001).

Applicant's invention does not apply, involve, use, or advance the technological arts as previously set forth by the examiner, in Paper No. 6. Thus, for the reasons set forth above, the rejection of claims 1-3, and 5 is maintained.

***Rejection of Claims 1-3, 5-6 and 8 Under 35 U.S.C. § 102(b)***

Based upon Applicant's arguments the rejection under 35 U.S.C. § 102(b) is withdrawn.

***Rejection of Claims 4, 7, and 9 Under 35 U.S.C. § 103(a)***

The rejection of claims 4, 7, and 9 is withdrawn in light of the withdrawal of the 35 U.S.C. § 102(b) upon which these dependent claims were based.

***Lexicography***

After careful review of the specification and prosecution history, the Examiner is unaware of any desire—either expressly or implicitly—by Applicant(s) to be their own lexicographer and to define a claim term to have a meaning other than its ordinary and accustomed meaning. Therefore, the Examiner starts with the presumption that all claim limitations are given their ordinary and accustomed meaning. See *Bell Atlantic Network Services Inc. v. Covad Communications Group Inc.*, 262 F.3d 1258, 1268, 59 USPQ2d 1865, 1870 (Fed. Cir. 2001) (“[T]here is a heavy presumption in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art.”); *CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366, 62 USPQ2d 1658, 1662 (Fed. Cir. 2002) (There is a “heavy presumption that a claim term carries its ordinary and customary meaning.”). See also MPEP §2111.01 and *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).<sup>1</sup>

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<sup>1</sup> It is the Examiner's position that “plain meaning” and “ordinary and accustomed meaning” are synonymous. See e.g. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) (“[A]ll terms in a patent claim are to be given their plain, ordinary and accustomed meaning . . .”).

In accordance with the ordinary and accustomed meaning presumption, during examination the claims are interpreted with their “broadest reasonable interpretation . . .” *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).<sup>2</sup>

However, if Applicant(s) wish to use lexicography and desire a claim limitation to have a meaning other than its ordinary and accustomed meaning, the Examiner respectfully requests Applicant(s) in their next response to expressly indicate<sup>3</sup> the claim limitation at issue<sup>4</sup> and to show where in the specification or prosecution history the limitation is defined. Such definitions must be clearly stated in the specification or file history. *Bell Atlantic*, 262 F.3d at 1268, 59 USPQ2d at 1870, (“[I]n redefining the meaning of particular claim terms away from the ordinary meaning, the intrinsic evidence must ‘clearly set forth’ or ‘clearly redefine’ a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term”).<sup>5</sup> The Examiner cautions that no new matter is allowed.

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<sup>2</sup> See also MPEP §2111; *In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995); *In re Etter*, 756 F.2d 852, 858, 225 USPQ 1, 5 (Fed. Cir. 1985) (en banc).

<sup>3</sup> “Absent an *express intent* to impart a novel meaning, terms in a claim are to be given their ordinary and accustomed meaning. [Emphasis added.]” *Wenger Manufacturing Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1232, 57 USPQ2d 1679, 1684 (Fed. Cir. 2001) (citations and quotations omitted). “In the absence of an *express intent* to impart a novel meaning to claim terms, an inventor’s claim terms take on their ordinary meaning. We indulge a heavy presumption that a claim term carries its ordinary and customary meaning. [Emphasis added.]” *Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002) (citations and quotations omitted).

<sup>4</sup> “In order to overcome this heavy presumption in favor of the ordinary meaning of claim language, it is clear that a party wishing to use statements in the written description to confine or otherwise affect a patent’s scope must, at the very least, point to a term or terms in the claim with which to draw in those statements.” *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999).

<sup>5</sup> See also *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996), (“[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is *clearly stated* in the patent specification or file history. [Emphasis added.]”); *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998) (“Such special meaning, however, must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention.”). See also MPEP §2111.02, subsection titled “Applicant May Be Own Lexicographer” and MPEP §2173.05(a) titled “New Terminology.”

Failure by Applicant(s) in their next response to address this issue or to be non-responsive to this issue entirely will be considered a desire by Applicant(s) to forgo lexicography in this application and to continue having the claims interpreted with their ordinary and accustomed meaning and with their broadest reasonable interpretation. Additionally, it is the Examiner's position that above requirements are reasonable.<sup>6</sup> Applicant(s) are also cautioned that even though claim interpretation begins with this presumption, after issuance the prosecution history may further limit claim scope if Applicant(s) disclaim or disavow a particular interpretation of the claims during prosecution. *Abbott Laboratories v. TorPharm Inc.*, 300 F.3d 1367, 1372, 63 USPQ2d 1929, 1931 (Fed. Cir. 2002). Unless expressly noted otherwise by the Examiner, the preceding claim interpretation principles apply to all examined claims currently pending.

***37 CFR 1.105 Requirement for Information***

A 37 CFR 1.105 Requirement for Information is attached. A complete response to the enclosed Office action must include a complete response to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action, which is 3 months.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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<sup>6</sup> The requirements are reasonable on at least two separate and independent grounds: first, the Examiner's requirements are simply an express request for clarification of how Applicant(s) intend their claims to be interpreted. Second, the requirements are reasonable in view of the USPTO's goals of compact prosecution, productivity with particular emphasis on reductions in both pendency and cycle time, and other goals as outlined in the USPTO's The 21<sup>st</sup> Century Strategic Plan, June 3, 2002 available at [www.uspto.gov/web/offices/com/strat2001/index.htm](http://www.uspto.gov/web/offices/com/strat2001/index.htm).



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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Jeatran, et al. (5,989,586).

As per claim 6, Jeatran teaches a computer implemented method for tracking samples of a clinical study (Abstract), comprising the steps of:

Providing a computer having an associated memory (Fig. 3 – 61);

Providing a list of standard operating procedures, wherein each of said standard operating procedures comprise procedure steps (The Clinical Study Protocol/enrollment verification criteria verification, collection of patient response information, and changing of the individual patient treatment during the study based on the specific criteria – each study includes a set of specific minimum standards or enrollment criteria that each participant or patient must meet to be included in the study which is utilized to comprise the procedure steps, see col. 6);

Providing a list of samples (Fig. 1); and

Merging said list of standard operating procedures with said list of samples to generate a check list for use in connection with said clinical study, wherein said list of standard operating procedure, said list of samples and said checklist are all stored in said computer memory (Figs. 2-33).

As per claim 8, Jeatran teaches a computer implemented method for tracking samples of a clinical study (Abstract), comprising:

Accessioning a plurality of samples, wherein identifying information is stored in said computer (Figs. 2-33; col. 2, lines 11-32 – the sample, i.e. the drug is accessioned b/c the system is told what is being dispensed and identified by the identification number);

Determining procedures to be taken with respect to said samples, wherein said procedures comprise a plurality of steps (Figs. 6-7 – get appropriate medication, confirm assignment, collect more study specific data associated with the medication being given, i.e. the samples);

Defining at least a first workgroup comprising at least a first of said plurality of samples (Abstract - assigning at least one investigator to administer the contents of the plurality of bottles, i.e. the investigator is the at least one workgroup and the plurality of bottles is the plurality of samples), wherein said first workgroup comprises at least one procedure (Abstract - administering the contents is the at least one procedure), and wherein said one workgroup is stored in said computer (providing sponsor computer means including telephone capabilities and for storing information, disseminating information, and instructions over the telephone to the investigators, and for receiving information from the investigators, the computer means operable, upon being contacted by the investigator and requiring caller identification Fig. 4 – 65, 66 and 67 in order to authenticate, i.e. the computer stores the workgroup);

Preparing at least one checklist comprising said at least a first workgroup and said steps comprising said at least one procedure, wherein said checklist is stored in said computer (Figs. 2-33 and Abstract);

Performing said steps (Figs. 2-33 and Abstract);

Recording performance of said steps in said computer (Figs. 2-33 and Abstract).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran (5,898,586) as applied to claims 6 and 8 above, and further in view of William E. Evans and Mary V. Relling, Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics, Science, Vol. 286, Issue 5439, October 15, 1999, pp. 487-491.

Jeatran teaches as set forth above. However, Jeatran does not teach that one of the procedures determines the genotype of an individual, although Jeatran does teach that study specific data may be collected (Fig. 7 – 118). Evans teaches determining the genotype of an individual in conjunction with clinical studies. Evans further teaches that determining an individual's genotype is associated with disease risk and drug toxicity, is likely to constitute part of the mechanism for so-called "idiosyncratic drug reactions, drug –metabolism genotypes may result in a phenotype in the absence of drug, and that common polymorphisms in drug targets dictate that DNA sequence variations be taken into account in the genomic screening processes aimed at new drug development to provide new insights for the development of medications that target critical pathways in disease pathogenesis and medications that can be used to prevent diseases in individuals who are genetically predisposed to them. (Pp. 1-4 of 8 and Fig. 3) Evans thus teaches that automated systems are being developed to determine an individual's genotype for polymorphic genes that are known to be involved in the pathogenesis of their, disease, in the metabolism and disposition of medications, and in the targets of drug therapy, which need be performed only once for each battery of genes tested and can then become the blueprint for individualizing drug therapy. (Pg. 6 of 8 and Fig. 3) Therefore, it would have been obvious to

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one of ordinary skill in the art at the time of the invention to have included determining an individuals genotype as taught by Evans into the system and method of Jeatran for the specific reasons set forth in Evans.

Claims 1, 3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran, et al. (5,898,586).

As per claim 1, Jeatran teaches a method for tracking samples of a clinical study (Abstract), comprising:

**Defining a first clinical study protocol comprising a plurality of procedures, wherein said procedures comprise steps;**

Accessioning samples for said first clinical study protocol by recording in a database identifying information for said samples and identification of said first clinical study (col. 2, lines 11-32 – the sample, i.e. the drug is accessioned b/c the system is told what is being dispensed and the study is identified b/c it is the only study for which the data is being recorded, it is the first because it is the only one being recorded and there is no other one claimed);

Creating a worklist by assigning a particular scientist to perform a particular procedure on particular samples (Abstract; Figs. 4 and 13; col. 2, lines 11-32 – particular scientists/investigators are assigned to perform, i.e. administer the samples, a particular procedure on particular samples, the “worklist” is in essence created when the computer system provides the medications, and creates and identity check by study id and PIN and performing a match before returning the checklist);

Creating a checklist comprising the steps of at least one procedure to be performed on the samples of a worklist (Abstract; Figs. 3-33 – the checklist is a verbal list via the telephone that is input by the scientist/investigators based on the sample and the patient);

Performing the steps on the checklist (Abstract; Figs. 3-33 – the steps are walked through to ensure that compliance with the protocol is met);

Recording in said database completion and results of at least a portion of said steps on said checklist (Abstract; Figs. 3-33, i.e. commit randomization file and patient file changes to the database step 131, commit changes to database step 179, save bottle status step 178).

Jeatran teaches as set forth above. However, Jeatran does not specifically teach that clinical protocols encompass multiple procedures, although Jeatran does teach the specific procedure steps set forth. The examiner takes Official Notice that clinical protocols must be developed and approved and that they encompass multiple procedures. Evidence to support this statement includes the fact that there are multiple regulations governing the design of clinical protocols in various countries, new drug design is more complex and proving the efficacy and safety can be critical to the manufacturer and it can take over eight years for a new drug to get FDA approval and includes multiple clinical studies, under a clinical protocol, which are the premarket testing ground for unapproved drugs to evaluate safety and effectiveness in treating, prevent, or diagnosing a specific disease or condition. See, e.g. CDER Handbook, pp. 3-29. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included an approved clinical study, i.e. defined clinical study, which encompass multiple procedures, to modify Jeatran because a clinical study involving human beings and pharmaceuticals can not be conducted without such a protocol. Alternatively, pharmaceutical companies would want to

ensure that they have complete documentation that they have done everything in their power to ascertain the safety of a drug/pharmaceutical before releasing it for general consumption due to the huge liability risks involved, for example Eli Lilly and defense of the Prozac litigation.

As per claim 3, Jeatran teaches the step of indicating completion and results of at least a portion of said steps on said checklist comprises indicating completion of at least one step for all samples on a checklist by one entry of information (Figs. 3-33, commit randomization file and patient file changes to the database step 131).

As per claim 5, Jeatran teaches the step of formalization of the results by an activity selected from the group consisting of entry of new results (Figs. 3-33, commit randomization file and patient file changes to the database step 131).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran (5,898,586) as applied to claim 1 above, and further in view of Oku, et al. (5,675,745) and in view of Tony Kennedy, Pharmaceutical Project Management, Vol. 86, 1998, pp. 109-112.

Jeatran teaches as set forth above. Jeatran does teach that the study id and the investigator id must match before access to the checklist can proceed (Fig. 13). However, Jeatran does not teach conducting the method steps with a second clinical study protocol. Kennedy teaches that because of the small size of some departments and the lack of sufficient numbers of qualified individuals within departments, many managers wind up assigning one person to more than one project team, i.e. a second clinical study protocol (pg. 111). Oku teaches that multiple clinical trials can be contained within the same system (Fig. 46), that the Workgroup list for a specific clinical trial can be accessed (Figs 48 and 49), and that work management can be entered as assigned to a specific person for a specific task (Fig. 54). Oku

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further teaches that the database employs GCP, and that the work side model is made by employing the network used in the project management and stratifying roughly in the sequence of phase, clinical trial, working group, and work, i.e. by relating various documents with work flow, it is possible to retrieve form other standpoints than structure of the document itself, such as job flow (col. 20, lines 21-60). Oku further teaches that you can drill down through the clinical trial to get to work progress list for each clinical trial (cols. 21-22, lines 50-52). Thus, Oku teaches that through the documents and project management tasks are allocated with instructions according to the protocol/SOP and recorded in multiple clinical trials (Figs. 46, 48, 49, 54 and 58-62; cols. 20-22). Moreover, Oku teaches that research and development, was not being adequately addressed, as there existed a need to enhance productivity of routine tasks and non-routine tasks that can be addressed by standardized procedures (col. 1, lines 31-54). Thus, it would have been obvious to have incorporated a second clinical trial into Jeatran as Kennedy teaches the need for reuse of personnel and Oku teaches that the implementation of multiple clinical trials for enhanced efficiency.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran (5,898,586) as applied to claim 1 above, and further in view of William E. Evans and Mary V. Relling, Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics, Science, Vol. 286, Issue 5439, October 15, 1999, pp. 487-491.

Jeatran teaches as set forth above. However, Jeatran does not teach that one of the procedures determines the genotype of an individual, although Jeatran does teach that study specific data may be collected (Fig. 7 – 118). Evans teaches determining the genotype of an individual in conjunction with clinical studies. Evans further teaches that determining an

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individuals genotype is associated with disease risk and drug toxicity, is likely to constitute part of the mechanism for so-called “idiosyncratic drug reactions, drug –metabolism genotypes may result in a phenotype in the absence of drug, and that common polymorphisms in drug targets dictate that DNA sequence variations be taken into account in the genomic screening processes aimed at new drug development to provide new insights for the development of medications that target critical pathways in disease pathogenesis and medications that can be used to prevent diseases in individuals who are genetically predisposed to them. (Pp. 1-4 of 8 and Fig. 3) Evans thus teaches that automated systems are being developed to determine an individual’s genotype for polymorphic genes that are known to be involved in the pathogenesis of their, disease, in the metabolism and disposition of medications, and in the targets of drug therapy, which need be performed only once for each battery of genes tested and can then become the blueprint for individualizing drug therapy. (Pg. 6 of 8 and Fig. 3) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included determining an individuals genotype as taught by Evans into the system and method of Jeatran for the specific reasons set forth in Evans.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

W0 99/63473 discloses a clinical trial data management system and method including a list of work to be completed.

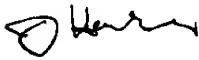


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is 703.306.2906. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703.308.5183. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9326.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1113.



Jennifer Ione Harle  
December 14, 2003



ROBERT P. OLSZEWSKI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600

## 37 CFR § 1.105 - Requirement for Information

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

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1. The information is required to extend the domain of search for prior art. Limited amounts of art related to the claimed subject matter are available within the Office, and are generally found in class 705 and subclasses 1, 2, 3, and 9 which describes generalized workflow for hospitals and physicians offices and dosing in blind studies and work flow in general for creating new projects and adding project tasks and resources to the system; class 395 and subclass 207, which describes making a real model defining the concept handled in the organization, i.e. registering various pieces of information generating in the process of various organization activities based on the result of taking in and analyzing event in consider of process (work flow ) management, organization internal rules, statutory regulations, etc. as it pertains to the example of the pharmaceutical industry and clinical trials; class 514, subclass 317 which describes methods and kits for determining appropriate treatment for illnesses in humans utilizing drugs and placebos; class 706 subclass 50 which describes managing applied knowledge and workflow in multiple dimensions and contexts where an activity manager assigns activities and tasks to done, verifies completion of the tasks, and possibly initiates re-assessments; class 707, subclasses 104 and 500 which describe workflow in general and a digital computer system in a clinical testing laboratory assays free Beta in a biological sample obtained from a pregnant patient and uses the resulting data, along with other patient and reference data, to create a patient profile; class 702, subclass 22 which describes automated laboratory software architecture for laboratory machines. A broader range of art to search is necessary at a minimum to establish the level of knowledge of those of ordinary skill in the claimed subject matter art of the workflow management procedures utilized in clinical trials/studies/protocols from the initial phase to the laboratory/scientist level with or without computers, i.e. are they the same as workflow management for other organizations, taking into account GCP.

The information is required to document the level of skill and knowledge in the art of at a minimum to establish the level of knowledge of those of ordinary skill in the claimed subject matter art of workflow management procedures utilized in clinical trials/studies/protocols from the initial phase to the laboratory/scientist level with or without computers.

2. In response to this requirement, please provide a list of keywords that are particularly helpful in locating publications related to the disclosed art of clinical trials/studies/protocols from the initial phase to the laboratory/scientist level with or without computers.

3. In response to this requirement, please provide a list of citations to electronically searchable databases or other indexed collections containing publications that document the knowledge within the disclosed art of clinical trials/studies/protocols from the initial phase to the laboratory/scientist level with or without computers.

4. In response to this requirement, please provide the citation and a copy of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matter of clinical trials/studies/protocols from the initial phase to the laboratory/scientist level with or without computers.

5. Any information in the possession of the inventors or assignee pertaining to the work flow for clinical trials/studies/protocols, which would include declarations, etc.. See, e.g. Peter Villiers, New Architecture Linkage of SAS/PH-Clinical Software with Electronic Document Management Systems, June 19, 1997 (a collaborative effort between SAS and Xerox, which one of the inventors, Igor Markidan, worked with and cited in his Patent 6,236,994 B1).

These paragraphs require copies of art relied upon for the description of the prior art or the development of the invention and drafting of the claims. These requirements are close ended in that only those documents actually relied on rather than documents believed to be relevant are required.

6. In response to this requirement, please provide the citation and a copy of each publication that any of the applicants relied upon to develop the disclosed subject matter that describes the applicant's invention, particularly as to developing the steps b of creating a worklist and creating a checklist of claim 1 and claim 2. For each publication, please provide a concise explanation of the reliance placed on that publication in the development of the disclosed subject matter.

7. In response to this requirement, please provide the citation and a copy of each publication that any of the applicants relied upon to draft the claimed subject matter. For each publication, please provide a concise explanation of the reliance placed on that publication in distinguishing the claimed subject matter from the prior art.

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The fee and certification requirements of 37 C.F.R. § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 C.F.R. § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 C.F.R. § 1.105 are subject to the fee and certification requirements of 37 C.F.R. § 1.97.

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The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete response to the requirement for that item.

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This requirement is an attachment of the enclosed Office action. A complete response to the enclosed Office action must include a complete response to this requirement. The time

period for reply to this requirement coincides with the time period for reply to the enclosed Office action, which is 3 months.

The period for reply to an office action on the merits is ordinarily set for 3 months.

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 12/18/03

ROBERT P. OLSZEWSKI  
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